UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456 Civil Action No. 01-12257-PBS
	)	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	)	

THE SCHERING-PLOUGH GROUP'S INDIVIDUAL
MEMORANDUM IN OPPOSITION TO CLASS CERTIFICATION

PRELIMINARY STATEMENT

The "Schering-Plough Group" encompasses two distinct companies, Schering Corporation and Warrick Pharmaceuticals, eighteen brand name drugs manufactured by Schering, and ten generic drugs sold by Warrick. These drugs are marketed by different employees to different purchasers in different segments of the pharmaceuticals market. Even as to Schering or Warrick standing alone, the unprecedented classes Plaintiffs have proposed could never be certified.

As to Schering and Warrick, just as to the other defendant groups, Plaintiffs cannot show that common questions of law and fact predominate over questions affecting individual class members.[1] Individualized proof will be required of each market participant's knowledge of the meaning of AWP as well as the impact, injury and damages, if any, it suffered as a result of the AWP scheme alleged in the AMCC. Plaintiffs' proof of these elements of its claims will necessarily involve whether, how, and to what extent each putative class member was harmed by the publication of Schering's or Warrick's AWPs based on a detailed analysis of the contractual relationships between the payor and the PBM or the payor and the provider to determine the actual effect of AWP on reimbursement rates.

This separate brief is devoted to an additional factor that precludes certifying a class with respect to generic or multiple-source drugs such as those sold by Warrick. Third-party reimbursement for multiple-source and generic drugs is not generally based on AWP, but on a privately-negotiated Maximum Allowable Cost or "MAC." Young

[1] The Schering-Plough Group joins the Fast Track Defendants' Memorandum in Opposition to Class Certification as well as the individual briefs filed on behalf of each of the Fast Track Defendants.

Report ¶ 89. In those few instances in which pricing even refers to AWP, it typically is based on the median AWP of the class of drugs to which it belongs and thus on an AWP published for some other manufacturer's drug. Plaintiffs' legal theory – that the reported AWP for each drug was fraudulent and caused damage because, on a transaction-by-transaction basis, each plaintiff paid for those drugs based on the allegedly fraudulent statement – ignores the separate pricing and marketing system unique to the multiple source and generic market. Thus, Warrick's published AWPs could not have defrauded Plaintiffs, and transactions involving reimbursement for multiple-sources drugs cannot be included in the class.

I. Warrick Participates in a Generic Market that is Uniquely Competitive

Warrick Pharmaceuticals Corporation ("Warrick") is a wholly-owned subsidiary of Schering Corporation. Schering Corporation, in turn, is a wholly owned subsidiary of Schering-Plough Corporation. *See* Declaration of Harvey J. Weintraub at ¶ 2 (hereinafter "Wein. Dec."), attached hereto as Exhibit 1. Unlike Schering and the other fast-track defendants, Warrick manufactures and distributes exclusively generic products – that is, products that are bioequivalent to drugs that are no longer subject to patent protection. Many of Warrick's generic products were first researched and developed by Schering and were once single-source products marketed under a Schering brand name. As patent exclusivity expires on Schering products, Warrick has often taken them into its generic marketing portfolio in an effort to offset the impact of inevitable generic competition. For example, Warrick markets generic albuterol-sulfate, which is the same chemical compound as Schering's Proventil. Wein. Dec. ¶ 5

The generic market in which Warrick operates differs fundamentally from the branded market, and there is a typical competitive path that most generic drugs follow. Under the Hatch-Waxman act, the first generic that enters the market is granted a 6-month exclusivity period during which other generics cannot compete with it. As a result, the first generic is generally priced somewhat below that of the branded version and does not significantly discount during that 6-month period. Young Report ¶ 181. As other generics become eligible to enter the market, they tend to set their list price close to that established by the first generic manufacturer, but as competition increases, all generic versions are discounted at ever-greater discounts off the list price (assuming they have a list price, which Warrick does not). Young Report ¶ 182; Wein. Dec. ¶ 12.

The competitive dynamic in the generic market is further enhanced throughout the distribution chain because many parties have some control over whether and which generic is dispensed. Young Report ¶ 178. Generic drugs are essentially fungible and customers, who often command significant market share, generally stock a single product for each bioequivalent. Wein. Dec. ¶ 9. Thus, pharmacies often stock only a single manufacturer's generic product and dispense only that product. Young Report ¶ 182. At both the pharmacy and wholesaler level, the decision-maker is commonly responsible for multiple stores, or even for nationwide distribution, and purchases product that will be dispensed to customers reimbursed by numerous and various third-party payors. Competition (predominately on price) for stocking on pharmacy shelves is fierce because generics are interchangeable at the outset, and advantages of early acceptance are great. Wein. Dec. ¶ 8.

Physicians, health plans, and PBMs also exercise significant control or influence over the use and selection of generic drugs. For example, a physician may write a prescription for a given branded product or its generic equivalent. Unless the physician specifically states on the prescription, however, that a generic product may not be substituted for the branded product, the pharmacy filling the prescription may be obligated to dispense the generic equivalent. Similarly, generic substitution programs chosen by plans, and run by PBMs, can also make this outcome more likely by offering financial incentives to patients and pharmacies in the form of differing co-pays and dispensing fees, respectively, to utilize generics. Young Report ¶ 179. Plans can further dictate the extent to which generics are dispensed through formulary restrictions.

A reflection of the generic marketplace, Warrick has only approximately eighty customers, but through those customers commands a major share of the generic albuterol-sulfate market. *Id.* Warrick competes on a number of bases, including the breadth of its product portfolio, production capacity, customer service levels, and price. Wein. Dec. ¶ 10. Warrick also offers its customers certain discounts and rebates, including prompt pay discounts, volume-based rebates, and stocking allowances. *Id.* As a critical element of its pricing, Warrick often agrees to a right of first refusal on price under which it typically meets, but does not beat, lower prices offered by competitors to significant customers on existing inventory previously purchased by the customer. Wein. Dec. ¶ 10.

In the context of this unique competitive environment, where prices fluctuate frequently, Warrick reports reference pricing information to national pricing compendia. Wein. Dec. ¶ 11. At the time of launch, Warrick has generally reported an AWP at 10%-20% below the equivalent brand product's AWP. Thereafter, AWP has generally

remained constant over time. *See* Exhibit A to AMCC. Because Warrick's wholesale and retail customers are invoiced at a wide range of different prices, and because those prices change so frequently and are subject to subsequent adjustment, it is not possible to determine or report a wholesaler list price (or WAC) to national pricing compendia. Wein. Dec. ¶ 12. Similarly, Warrick cannot report a single AWP that would have a uniform relationship to the multitude of changing prices at which it sells it drugs. Wein. Dec. ¶ 13. Accordingly, Warrick has simply suggested an AWP at launch and has, in almost all instances, left it untouched for the life of the product. *Id.*

II. Reimbursement for Generic Drugs by Third-Party Payors Is Typically Based on MAC Pricing And Therefore Is Not Tied to the Manufacturer's AWP

Plaintiffs' proposed classes have been changed to payors who reimburse for a drug "based on contracts that expressly use AWP as a pricing standard." Motion for Class Certification, ¶ 1. While Plaintiffs acknowledged in the AMCC that reimbursement for multiple-source drugs by private payors often is based on MAC rather than AWP, AMCC ¶ 181, they alleged nevertheless that "reimbursement is closely tied to the published AWP for a generic drug." *Id.* at ¶ 183.[2] In fact, however, MACs are privately set price points that have little or no relationship to AWP. Plaintiff's own experts now confirm that there is no evidence that MAC prices are set by reference to AWP:

> Pharmacy Benefit Managers usually create their own MAC lists. By creating MAC price lists, PBMs claim to seek to provide incentives to their clients to induce retail pharmacies to use cost-effective generic drugs. This mechanism was developed in response to the wide variation in the

[2] Although the private payor market generally uses the term "generic" rather than "multiple-source" the two are interchangeable for current purposes. Warrick markets exclusively generic drugs and Schering markets both single and multiple-source drugs. Declaration of Debra Kane at ¶ 5, attached hereto as Exhibit 2.

> price of bioequivalent drugs. *However, how TPPs actually define MAC and the extent to which the TPPs strictly enforce MAC are unknown.*

Hartman Decl., Attachment D, ¶ 37 (emphasis added). As stated in the response of National Prescription Administrators (a PBM) to the request for proposals from named plaintiff UFCW, "the MAC will replace Average Wholesale Price for the selected drugs in determining the ingredient cost, without regard to the drug's published AWP." Young Report ¶ 190.

The evidence demonstrates that there is, in fact, no one established practice or consistent manner by which MACs are calculated. Young Report ¶ 185. PBMs and Health Plans each separately develop a "MAC list" for the maximum amount they will reimburse for the generics they cover. *Id.* PBMs and Health Plans consider their MAC lists to be highly confidential trade secrets because they utilize proprietary methodologies for determining the MAC listed. Young Report ¶ 187. As such, MAC lists differ from PBM to PBM, and can differ from contract to contract for a particular PBM.

In establishing MAC prices, a variety of factors may come into play, including some or all of the following: actual cost; usual and customary charges ("U&C"); Health Care Financing Administration ("HCFA") MAC price; Federal Financial Participation Reimbursement ("FFP"); General Prescriptives Program ("GPP"); Federal Upper Limit ("FUL"); WAC; First DataBank's published baseline price; and AWP. Gaier Report ¶ 66; *see also*, Young Report ¶ 189. For example, a 2002 agreement between plaintiff Twin Cities Bakery Workers Health and Welfare Fund ("Twin Cities") and Caremark indicates that MAC is derived from several pricing information sources, including the WAC and the FUL. *Id.* In a 1995 contract between Coventry [full name] and Express Scripts, MAC is defined as the "maximum price for certain generic and multi-source

brand prescription drugs established by ESI from time to time using a variety of factors, including but not limited to the First DataBank's/Medispan's published baseline price and the maximum allowable cost determined by the Health Care Financing Administration." *Id.* By contrast, Express Scripts 1999 proposal to the Teamsters simply determines MAC by using "AWP and discounts." *Id.*

Whether and to what extent a pharmacy is reimbursed for a generic drug dispensed at a price other than MAC, such as the drug's usual and customary cost, requires analysis of transactional level data. This determination, including whether the pricing involved any consideration of AWP, requires an entity-by-entity analysis. Young Report ¶ 192. For those entities that nominally use AWP as one of several factors in determining MAC, a contract-by-contract analysis will be necessary to determine the effect of the consideration of AWP as compared to the other factors used to derive MAC. Empirical evidence shows that reimbursements identified as paid with reference to AWP may actually bear no relationship to AWP. Gaier Report ¶ 68, Figure 6. Many contracts that expressly reference AWP as a pricing standard are actually paid with reference to AWP only in conjunction with a variety of other factors which limit – if not eliminate – the effect of AWP on reimbursement rates. Gaier Report ¶ 69. Therefore, the determination of whether, as alleged by plaintiffs, a payor paid an inflated price for a drug because of an inflated reported AWP, cannot be made on a common basis. Young Report ¶ 224.

Even when MAC prices are nominally set with reference to AWP, they are often based on the median of the AWPs for multiple manufacturers. Gaier Report ¶ 67. The reliance on a median AWP destroys any linkage between any individual defendant's

reported AWP and a payor's price for a prescription drug. *Id.* The established MAC for a generic, as well as the median AWP for the class of generics, determines reimbursement rates for all versions of the generic, regardless of manufacturer. Young Report ¶ 223. The fixed reimbursement rate therefore renders irrelevant to the ultimate Payor the pharmacy's selection of a specific manufacturer's version of the product because the reimbursement paid is unaffected by the pharmacy's selection process. Young Report ¶ 186.

"Auto-substitution" programs operated by wholesalers and distributors for the sale of generics create additional individual issues, rendering certification of a class inappropriate with respect to generics. An auto-substitution program is a type of elective plan offered by wholesalers and distributors to their customers for the sale and purchase of generic products in which a customer agrees to allow the wholesaler/distributor to determine which particular manufacturer's generic product will be used to fill an order for a given generic drug. Young Report ¶ 108. In such a program, a customer merely submits a purchase order for a generic product and the wholesaler or distributor alone decides which manufacturer's product is used. Neither AWP nor the "spread" can be a determinant in the decision about which drug a customer receives pursuant to an auto-substitution program because the customer necessarily cannot choose from among different AWPs or "spreads" for these products and the wholesaler or distributor makes its decision about which manufacturer's product to utilize based upon its cost.[3] *Id.* AWP, therefore, is eliminated as a consideration with regard to what drug is dispensed.

[3] Based on forthcoming discovery and discovery in related cases, cost is the principal determinant upon which wholesalers and distributors decide which manufacturer's product is utilized in auto-substitution programs.

III. Reimbursement for Generic Drugs Under Medicare Part B Is Not Tied to a Defendant's Published AWP

Reimbursement for generic drugs under Medicare Part B is also independent of the AWP of a particular defendant. By federal regulation, reimbursement for multiple-source drugs under Medicare Part B is based on the median AWP rather than the AWP published for any particular defendant. *See* 42 C.F.R. § 405.517 (specifying that reimbursement is "the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological"). Plaintiffs' allegations for generic drugs are inconsistent with the mantra of the AMCC that defendants compete by marketing larger spreads to entities within the distribution chain that have the ability to move market share. One manufacturer simply cannot obtain a competitive advantage over another by increasing the AWP for its drug. Any effect that such an increase would have on Medicare payments would apply equally to all forms of the drug.

Plaintiffs confront many of the same individualized inquiry problems in the Medicare Part B context that they face in the private payor arena. Where reimbursement is based on a "median AWP," it is by definition not based on the AWP published for each individual defendant. Consequently, the reimbursements for a particular manufacturer's drug may increase when a competing manufacturer raises its AWP. Alternatively, a manufacturer may raise its AWP with no effect on reimbursements. Therefore, because there is no linkage between a Payor and an individual defendant's AWP, a single manufacturer's AWP cannot have caused injury.[4] Gaier Report ¶ 67. Furthermore, under

[4] It is important to note that the "median" is a value in an ordered set of values below and above which there is an equal number of values or which is the

this reimbursement system, one amount is reimbursed for all competing drugs. Under Medicare a manufacturer cannot use its AWP to make its reimbursement level higher than that of its competitors. There is, in short, no competitive advantage gained by inflating AWP for multi-source drugs reimbursed under Medicare. Young Report ¶ 228.[5]

In sum, no class can be certified with respect to generic drugs. Plaintiffs' own experts – and discovery taken of plaintiffs to date – confirms that reimbursement is rarely based on the AWP published for a particular defendant's own drug. Identifying those few instances in which reimbursement for a particular defendant's generic drug was based on the AWP published for that particular defendant would require analysis of a myriad of individual issues on a transaction-by-transaction basis. The Court should deny defendant's motion for class certification to the extent it seeks to include transactions for multiple source and generic drugs.

CONCLUSION

For all the foregoing reasons, plaintiff's Motion for Class Certification should be DENIED.

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arithmetic mean of the two middle values if there is no one middle number. It is not an average. Consequently, even if each and every AWP above the middle number were increased by a factor of 10, the "median" value would not increase.

[5] Insofar as Plaintiffs attempt to overcome this fatal flaw by alleging that defendants act in unison by elevating AWP for all generic drugs, Schondelmeyer Decl. ¶ 33, not only is there no formal claim of conspiracy, the allegation is flatly contradicted by the documents attached as Exhibit A to the AMCC (charting AWP reported in Appendix A to the AMCC for each of Warrick's generic drugs). As shown in that exhibit, Warrick generally sets the AWP for its generic drugs at the time of launch at 10-20% below the published AWP of the corresponding branded drug, and does not change that AWP over time. Wein. Decl. ¶¶ 11, 13.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by Verilaw posting on October 25, 2004.

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